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09/463,705    02/23/00    CORTES

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EXAMINER
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RAO, M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/28/01

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BIERMAN MUSERLIAN AND LUCAS  
600 THIRD AVENUE  
NEW YORK NY 10016

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/463,705**

Applicant(s)  
**Cortese et al.**

Examiner  
**Manjunath N. Rao**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Jun 12, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 2-16 and 20-45 is/are pending in the application

4a) Of the above, claim(s) 4, 7-14, 16, 20-41, 44, and 45 is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 2, 3, 5, 6, 15, 42, and 43 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

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### **DETAILED ACTION**

1. Claims 2-16, 20-45 are now pending in the application.

#### ***Election/Restriction***

2. Applicant's election with traverse of Group I, Claims 2-15, 42, 43 in Paper No. 18, 3-20-01 is acknowledged. Applicant's election of the polynucleotide *eryBII* (and its corresponding polypeptide sequence SEQ ID NO:2) as a single species in Paper No. 20 is also acknowledged. Due to the election of *eryBII* polynucleotide (and its corresponding polypeptide) only claims 2, 3, 5, 6, 15, 42 and 43 have been considered. Claims 4, 7-14 drawn to other polynucleotides and polypeptides have been withdrawn from consideration.

Applicant's traversal is on the ground(s) that the different inventions of Groups I-X and the 11 polynucleotides and their respective 11 polypeptides corresponds to a single invention. This is not found persuasive to overcome the restriction or the species election because each of the 11 polynucleotides have different structure and different function, i.e., they encode different polypeptides. Furthermore, each of the encoded polypeptide has different activity as an enzyme and hence constitute separate and independent inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 7-14, 16, 20-41, 44-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper Nos. 18 and 20.

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***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority under 35U.S.C. 119(a)-(d). The certified copy has been filed in parent PCT Application No. PCT/FR98/01593, filed on 7-21-1991.

***Drawings***

4. This application has been filed with drawings that have been objected to by the Draftsperson. Please see the attached form PTO948 for details.

***Claim Objections***

5. Claim 3 is objected to because of the following informalities: Claim 3 improperly spells the word "An" as "Am". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the phrase "sequences which hybridize". Applicants do not provide the conditions under which hybridization can occur. Absent this information it is not clear to the

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Examiner as which DNA sequences applicants are claiming, because any DNA sequence that can hybridize under any hybridization condition (including non-specific hybridization under low stringency) will read on the above claim.

8. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the phrase “display significant homologies”. It is not clear to the Examiner as to what level of homology, applicants consider as significant. Providing a numerical value to the homology level (such as 95% homology or the like depending on the support in the specification) that applicants desire would overcome this rejection.

9. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the phrase “analogues of this polypeptide”. It is not clear to the Examiner as to what applicants mean by “analogues”. A perusal of the specification indicates no clear definition of “analogues” of the above polypeptide.

10. Claim 15 provides for the use of the *eryBII* DNA sequence, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is

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intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

11. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear to the Examiner whether claim 42 is directed only to SEQ ID NO:1 or fragments thereof. Literal language in the claim indicates that it is directed to only SEQ ID NO:1 but dependent claims recite fragments. It is not clear to the Examiner whether these fragments are any fragment/s or fragment/s encoding ORFs.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 16 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules which hybridize and/or display significant homologies with SEQ ID NO:1 (nucleotide 48 to 1046) or fragments of SEQ ID NO:1.

The specification does not contain any disclosure of the structure of all DNA sequences that hybridize and/or display significant homologies to SEQ ID NO:1 or fragments of SEQ ID NO:1. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of having different structure and function. Therefore, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

13. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 is directed to any peptide encoded by SEQ ID NO:1 (interpreted to include peptide fragments) and claim 6 is directed to polypeptides corresponding to analogues of SEQ ID NO:2. Claims 5, 6 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO:2 including modified polypeptide sequences that have not been disclosed in the specification. No description has been provided of the analogous polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:2 has been provided by applicants which would indicate that they had possession of the claimed genus of analogous polypeptides. The specification does not contain any disclosure of the structure and function of all the polypeptide sequences within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structure and function. Therefore many structurally and functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.



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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 2, 3, 5, 6, 15, 42 and 43 are rejected under 35 U.S.C. 102(a) as being anticipated by Summers(a) et al. (WO 97/23630, 3 July, 1997, Also see accession no. AAW19736 AAT72684 on Genseq database) . This rejection is based upon the public availability of a printed publication. Claims 2, 3, 5, 6, 15, 16, 42 and 43 of the instant application are drawn to a polynucleotide sequence comprising the *eryBII* sequence corresponding to ORF7 (nucleotides 48-1046 of SEQ ID NO:1) encoding dTDP-4-keto-L-6-desoxyhexose 2,3-reductase and DNA sequences which hybridize to the above polynucleotide or a homologous polynucleotide, the polypeptide encoded by the above polynucleotide, polypeptide with SEQ ID NO:2, its analogues, use of the polynucleotide to synthesize hybrid secondary metabolites in *Sac. erythraea*. Summers et al. disclose an identical polynucleotide encoding an identical polypeptide which can be used

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in preparation of secondary metabolites in *Sac.erythraea*. Therefore Summers et al. anticipate claims 2, 3, 5, 6, 15, 42 and 43 as written.

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

17. Claims 2, 3, 5, 6, 15, 42 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Summers(b) et al. (US 5,998,194 issued 12-7-1999, filed on 12-2-1995). This rejection is based upon the public availability of a printed publication. Claims 2, 3, 5, 6, 15, 16, 42 and 43 of the instant application are drawn to a polynucleotide sequence comprising the *eryBII* sequence corresponding to ORF7 (nucleotides 48-1046 of SEQ ID NO:1) encoding dTDP-4-keto-L-6-desoxyhexose 2,3-reductase and DNA sequences which hybridize to the above polynucleotide or a homologous polynucleotide, the polypeptide encoded by the above polynucleotide, polypeptide with SEQ ID NO:2, its analogues, use of the polynucleotide to synthesize hybrid secondary metabolites in *Sac.erythraea*. Summers et al. disclose an identical polynucleotide encoding an identical polypeptide which can be used in preparation of secondary metabolites in *Sac.erythraea*. Therefore Summers et al. anticipate claims 2, 3, 5, 6, 15, 42 and 43 as written.


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*Conclusion*

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao. Ph.D.  
August 27, 2001

  
**REBECCA E. PROUTY**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
1600